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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Bruce R. Davis

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EXAMINER

GORDON, BRIAN R

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/620,071	<b>Applicant(s)</b> DAVIS ET AL.	
	<b>Examiner</b> Brian R. Gordon	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11-17-06.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-21 and 23-27 is/are rejected.
- 7) ☒ Claim(s) 11 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed November 17, 2006 have been fully considered but they are not persuasive. Applicant asserts "Afeyan, et al. does not teach or suggest a fluid injection valve that is configured to selectively connect the outputs of two fluid selection valves to a sample vessel as claimed." The examiner respectfully disagrees valve 151 is equivalent to the injection valve as claimed for the valve 151 is structurally equivalent and capable of being switched to multiple positions. While one configuration is shown in figure 3, the reference discloses, "Valve 151 is a two-position three-channel valve, i.e., every other port is either placed in communication with the clockwise-adjacent port, or with the counterclockwise adjacent port (column 9, line 46." As such the valve can be positioned such that ports 5 and 6 are in communication thereby connected to the output of valve 116.

As to claim 3 the reference discloses "In the sample input section 115, a four-way mixing valve 116 is connected to a plurality of reservoirs 117a-d, which may contain different samples or buffers; for example, bovine serum albumin (BSA), a cell culture aliquot, a base, or water. (column 8, lines 55+)"

As to claim 5, as explained above the valve system of Afeyan is structurally capable of being configured to allow fluids to flow from the source containers through the components of the system including detector/sensor (136, 138) and port 5 of outlet valve 137.

As to claim 6, applicant asserts, "Pump 119 is connected to valve 151 and, regardless of the position of valve 151, is not connected to the columns 131,132." The examiner respectfully disagrees for the valve 151 when in position connecting ports 1 and 2 allows the pump 119 to communicate with the columns. Furthermore the reference discloses throughout "the second column being operative successively with or alternatively to the first column, pump means for providing variable pressure delivery of a solution to the column via the multiport valve, and program means for specifying a sequence of system control programs" (column 3, line 7 and Fig. 15A).

"The solvent input or delivery system 110 includes a plurality of solvent reservoirs 111a-f connected to respective ports of a six port four-way mixing valve 112, the mixed output of which is fed to a high pressure pump 113 which in the prototype embodiments is a dual piston pump with a capacity of 60 ml/minute at 2000-3000 psi, the high pressure output being delivered along 114 to input valve 151 for supply to the separation columns (column 8, lines 66+)."

As to the 103 rejection, the Afeyan disclose a desire to wash, (clean or purge the system) "the multi-port valve 134 may be turned to allow washing of column 132, after bypassing column 131, via a wash solution which flows into column 132 from port (6). The wash may exit column 132 via port (1) of valve 133." In such a process, it would have been obvious to recognize a foam or bubbles would evolve (column 17, lines 59+).

For reasons given herein the previous rejections are maintained as given herein.

In view of applicant's arguments the previous rejections of claims 11 and 22, are hereby withdrawn.

In the prior office action the examiner stated a number of the apparatus claims employ a number of "configured to" phrases which express and intended function of the elements and gave an example of claim 10. While applicant amended claim 11, applicant did not amend any of the numerous usage of the phrase within the remaining claims. For example, while the respective valves are recited as being configured to supply respective fluids. The examiner suggests applicant positive claim the respective plurality of fluid sources being connected to the ports of the respective valves, for such fluids are essential to the operation of the device.

#### **Claim Rejections - 35 USC § 102**

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-10, 13-15, and 17-21, 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Afeyan et al., US 6,344,172.

Afeyan et al. disclose method of using an analysis system the includes multiple valves, pumps, detectors, and solution reservoirs.

The device includes first and second selection valves (116, 112) with multiple ports and respective outlets (see col. 8, line 53 – col. line 13), fluid injection valves (151), sample vessels (131, 132), and analysis device (UV absorbance detector 136) (see figure 3; col. 10, lines 8-54), multiple pumps (113, 119, and others not labeled).

Art Unit: 1743

Valves 134 and 133 may also be configured so as to permit passage of effluent or eluant from second system column 132 to waste or to detector 136 (exhaust outlet/port).

As to claims 3-5, the claims employ "configured to" phrases, as such the source of rinse fluid is not considered an element of the invention. It's on required the device be structural capable of allowing for such connections to ports or the valves. One can choose to connect any other element to the ports as so desired.

FIG. 1 is a drawing of a commercial embodiment of the invention, which shows the protein separation apparatus of the invention substantially enclosed in a housing, along with a computer keyboard, mouse, and terminal in which data is collected and stored, and in which program control sequences are stored and executed.

Afeyan et al. discloses a calibration method. The device is calibrated by passing through the solute detector known concentrations of pure target solute so that concentration units can be correlated directly with, e.g., absorbance units (col. 24, 9-12).

### **Claim Rejections - 35 USC § 103**

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Afeyan as applied to claims 1-10, 13-15, and 17-21 and 23-27 above, and further in view of Hanson et al. US 4,108,602.

Afeyan does not disclose the device as comprising a bubble detector.

Afeyan does disclose the device including a switching means for cleaning and the desire to purge the sample line.

Hanson et al. discloses automated multiple sample chemical testing method and apparatus of the character wherein air pressure purging is employed, a to minimize

Art Unit: 1743

interference with sample detection from the presence of bubbles or foam which tend to be generated during any such air pressure purging.

As such it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Afeyan to detect bubbles which may arise from the cleaning process. Detection of such bubbles would allow for preventive measures to be taken to ensure the bubbles do not interfere with the sample detection.

### ***Allowable Subject Matter***

8. Claims 11 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: Afeyan does disclose mixing of fluids, however the mixing is not achieved using a separate mixing device to agitate or stir the fluids inside the analyzer of the system as disclosed by applicant.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, Telework Thurs., 1st Fri. Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BRIAN R. GORDON  
PRIMARY EXAMINER

Brian R Gordon  
Primary Examiner  
Art Unit 1743

brg

A handwritten signature in black ink, appearing to read 'BRG', with a long horizontal flourish extending to the right.